

November 4, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.95

Subject: GB Texas Newcastle Disease Challenge Virus

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum informs all interested parties of a change in the definition of Exotic Newcastle Disease (END) in 9 CFR 82.1 and the effect of this change on licensees, permittees, and applicants using the GB Texas strain of Newcastle disease virus (NDV) in research or production.

II. BACKGROUND

Until recently, APHIS has defined END to only include infection with viscerotropic, velogenic Newcastle disease viruses. On November 5, 1996, APHIS published a revision of 9 CFR 82.1 which defines END as any velogenic Newcastle disease (see Federal Register Vol. 61, pages 56877-56891). Under this revision, APHIS considers birds infected or exposed to the GB Texas strain of NDV (a neurotropic, velogenic virus commonly used as the challenge virus in efficacy and potency tests for both live and killed Newcastle disease vaccine) to be infected or exposed to END and subject to regulation under 9 CFR Part 82. This revision also requires that Center for Veterinary Biologics-Laboratory (CVB-L) not ship the GB Texas strain of NDV interstate unless a permit has been issued to the person receiving the virus (9 CFR Part 122).

Therefore, persons interested in obtaining GB Texas strain NDV from CVB-L must now obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors (transport permit) from Veterinary Services, National Center for Import-Export (NCIE).

III. GUIDELINES

A. How to Apply for a Transport Permit

1. *Complete and Submit VS Form 16-3* - Complete an application form, VS Form 16-3, "Application for Permit to Import Controlled Material or Import or Transport Organisms or Vectors" (enclosed), and submit it to NCIE, along with the current user fee.

2. *Additional Copies of VS Form 16-3* - To obtain additional copies of this form and instructions on the application process, do one of the following:

a. Call NCIE's automated document retrieval system at (301) 734-4952, request document numbers 1001 and 1005, and enter your fax number.

b. Access NCIE's web site at www.aphis.usda.gov/NCIE/imp-prod. Select "Import Application, VS Form 16-3," then "Cover page for VS16-3 Form in standard ASCII Format," or "Cover page for VS16-3 Form in PDF Format," and "pdf" for the form itself.

c. Call NCIE's main phone line at (301) 734-3277 and request the application form and instructions.

B. Permit Requirements

1. *Adequate Facilities and Procedures for Containment* - NCIE requires firms to demonstrate that they have adequate facilities and procedures to ensure containment of END before issuing a transport permit for interstate transport of any velogenic NDV. NCIE will contact Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) for information on whether facilities and practices at the firm are adequate to contain NDV.

2. *Approval of the State Veterinarian* - The applicant must obtain approval from the State Veterinarian to transport velogenic NDV into the State where the applicant's facilities are located. (For NCIE purposes this applies only to the original permit application, not for renewals.)

C. Facilities Requirements

To aid CVB-IC in providing the information necessary for NCIE to issue an organisms and vectors permit for transport of the GB Texas strain of NDV, veterinary biologics firms will need to amend their blueprints and legends that are on file with CVB-IC according to 9 CFR Part 108 to:

1. *Include NDV Strain Designations in the List of Organisms* - Specifically identify the GB Texas NDV challenge virus in the list of organisms permitted in the facility where appropriate.

2. *Show Where NDV is Stored and Handled* - Clearly show all locations where the GB Texas strain of NDV is stored and handled. Differentiate GB Texas NDV from other strains of NDV in the facility.

3. *Document Approval from the State Veterinarian* - Provide, as an addendum to facilities legends, evidence of the State Veterinarian's approval to bring GB Texas strain NDV into the State where facilities are located.

4. *Document Containment Conditions* - Show that facilities where all velogenic NDV is to be stored and handled comply with the following:

a. The facilities in which the firm conducts laboratory and animal studies meet the Biosafety Level 2 (BL-2) requirements described in the attached BL-2 Laboratory and BL-2 Animal Facility checklists.

b. There are no avian colonies within ½ mile of the facilities.

c. The firm does not permit personnel working with velogenic NDV to have contact with susceptible animal species and has instructed such personnel on the proper procedures for handling velogenic NDV.

d. The firm restricts access to NDV challenge materials and areas and requires special/dedicated clothing for direct contact with NDV challenge material or areas.

e. The firm has adequately protected laboratory and animal test facilities against insect and vermin infestation.

f. The firm's animal test facilities where work with velogenic NDV will be conducted have a separate air supply and exhaust system capable of containing the virus within the facility. This should include primary and secondary barriers and use of air flow. Blueprints and legends of the facilities should specifically document the types of filters used in all rooms where work with velogenic NDV will be conducted.

g. Facilities legends specify disinfectant products and procedures for use to contain routine spills and to disinfect the facilities before and after each animal study. In addition the firm:

(1) Disinfects all waste materials before disposal according to Veterinary Services Memorandum No. 800.56,

(2) Incinerates or autoclaves all carcasses on site,

(3) Transports all dead animals from the animal room directly to the incinerator or autoclave in leak-proof covered containers, and

(4) Conducts necropsies only in areas capable of containing the virus.

h. In the laboratory, employees conduct all work with the agent in a certified biosafety cabinet.

i. The firm conducts challenge tests with this virus in an isolator capable of containing the virus during the post-challenge observation period and decontaminates the isolator at the end of the study or test. The facilities legends include isolator specifications such as type of filters and air flow and outline specific procedures used to ensure containment of NDV within the isolator and to decontaminate the isolator when studies are concluded.

j. The applicant has notified the biosafety officer for the facility and gained his/her approval for the laboratory to obtain this material.

k. The facilities legends include any additional precautionary measures taken to contain the virus not covered above.

D. Facilities Inspections

CVB-IC will evaluate a firm's compliance with the containment conditions described in section C. 4. above as they conduct their normal establishment inspections. For initial issuance of a transport permit, the VS Area Office may also conduct inspections for such compliance. If APHIS inspectors have concern regarding the handling of the virus, or facilities documents have not been updated according to section C. of this memorandum, they will communicate this to NCIE. If this occurs, NCIE will issue no new permits and will not renew existing permits until the firm comes into compliance.

/s/ Thomas E. Walton for

Alfonso Torres
Deputy Administrator
Veterinary Services

4 Enclosures